

Type a plus sign (+) inside this box → ☐Approved for use through 9/30/98 PTO/SB/01 (4-96)  
OMB 0651-0032  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE**DECLARATION FOR  
UTILITY OR DESIGN  
PATENT APPLICATION**☒ Declaration OR  
Submitted with Initial Filing ☐ Declaration  
Submitted after Initial Filing

Attorney Docket Number ORTHOACIPCT.US

First Named Inventor KAY, DAVID B.

COMPLETE IF KNOWN

Application Number

Filing Date

Group Art Unit

Examiner Name

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

OPEN HELICAL ORGANIC TISSUE ANCHOR  
AND METHOD OF FACILITATING HEALING

the specification of which

(Title of the Invention)

☐ is attached hereto  
OR☒ was filed on (MM/DD/YYYY)

08/19/96

as United States Application Number or PCT International

Application Number

PCT/US96/13570

and was amended on (MM/DD/YYYY)

04/27/1997

(if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37 Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code §119 (a)-(d) or §385(b) of any foreign application(s) for patent or inventor's certificate, or §365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Not Claimed     | Certified Copy Attached? |                          |
|-------------------------------------|---------|----------------------------------|--------------------------|--------------------------|--------------------------|
|                                     |         |                                  |                          | YES                      | NO                       |
| NONE                                |         |                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                     |         |                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
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|                                     |         |                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|                                     |         |                                  | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

☐ Additional foreign application numbers are listed on a supplemental priority sheet attached hereto:

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below.

| Application Number(s) | Filing Date (MM/DD/YYYY) | <input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority sheet attached hereto. |
|-----------------------|--------------------------|--|
| NONE                  |                          |  |

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## DECLARATION

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I hereby claim the benefit under Title 35, United States Code §120 of any United States application(s), or §365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

| U.S. Parent Application Number | PCT Parent Number | Parent Filing Date (MM/DD/YYYY) | Parent Patent Number (if applicable) |
|--------------------------------|-------------------|---------------------------------|--------------------------------------|
| 08/517,259                     |                   | 08/23/1995                      |                                      |

☐ Additional U.S. or PCT international application numbers are listed on a supplemental priority sheet attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

| Name               | Registration Number | Name | Registration Number |
|--------------------|---------------------|------|---------------------|
| HUDAK, Daniel J.   | 25,879              |      |                     |
| SHUNK, Laura F.    | 31,423              |      |                     |
| LAFERTY, Samuel B. | 31,537              |      |                     |
| ROTE, Frank C. Jr. | 20,395              |      |                     |
| WEISZ, Louis J.    | 20,062              |      |                     |

☐ Additional registered practitioner(s) named on a supplemental sheet attached hereto.

Direct all correspondence to:


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|         |                                 | Fax       | 330-535-1435 |
|         |                                 | ZIP       | 44308-1133   |

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor:

☐ A petition has been filed for this unsigned inventor

|            |       |                |   |             |     |                 |
|------------|-------|----------------|---|-------------|-----|-----------------|
| Given Name | DAVID | Middle Initial | B | Family Name | KAY | Suffix e.g. Jr. |
|------------|-------|----------------|---|-------------|-----|-----------------|

|                      |   |      |        |
|----------------------|---|------|--------|
| Inventor's Signature |  | Date | 2/5/98 |
|----------------------|---|------|--------|

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|------|-------|-------|----|-----|-------|---------|----|

☐ Additional inventors are being named on supplemental sheet(s) attached hereto

RECEIVED - 02/19/98

1-10

Applicant or Patentee: David B. Kay  
Serial or Patent No.: \_\_\_\_\_  
Filed or Issued: \_\_\_\_\_  
Title: OPEN HELICAL ORGANIC TISSUE ANCHOR  
AND METHOD OF FACILITATING HEALING

Attorney's  
Docket No.: ORTHO-A

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS  
(37 CFR 1.9(f) & 1.27(b))--INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office regarding the invention entitled OPEN HELICAL ORGANIC TISSUE ANCHOR AND METHOD OF FACILITATING HEALING described in:

- ☒ the specification filed herewith.  
☐ application serial number \_\_\_\_\_, filed \_\_\_\_\_  
☐ patent number \_\_\_\_\_, issued \_\_\_\_\_

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below: \*

- ☒ No such person, concern, or organization  
☐ Persons, concerns or organizations listed below \*

\* Note: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

NAME \_\_\_\_\_  
ADDRESS \_\_\_\_\_  
☐ INDIVIDUAL ☐ SMALL BUSINESS CONCERN ☐ NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

David B. Kay  
NAME OF INVENTOR  
David B. Kay  
Signature of inventor  
8-23-95  
Date

NAME OF INVENTOR  
\_\_\_\_\_  
Signature of inventor  
\_\_\_\_\_  
Date

NAME OF INVENTOR  
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Signature of inventor  
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Date